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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,048	08/04/2003	Jallal Messadek	31927-CIP2	6961

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EXAMINER	
LEWIS, AMY A	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/635,048	MESSADEK, JALLAL	
	Examiner	Art Unit	
	Amy A. Lewis	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 33-37, drawn to a pharmaceutical antithrombotic combination, classified in class 514, subclass 453, for example.

II. Claims 12, 13, 31, 32, 38, 39, 40 and 41, drawn to a method of treating thrombosis and reducing or preventing the haemorrhagic side effects from the antithrombosis treatment by administration of the claimed compound (specifically glycine betaine), classified in class 514, subclass 396.

III. Claims 8, 9, and 10, drawn to a method of preventing or reducing the incidence or severity of a side effect of a therapeutically active agent having a possible hemorrhagic side effect, classified in class 514, subclass 396.

IV. Claim 11, drawn to a method of potentializing the therapeutic effect of a therapeutically active agent having a possible hemorrhagic side effect, classified in class 514, subclass 396.

V. Claims 14-30, drawn to a controlled release pharmaceutical system for delivering a compound in a time controlled manner, classified in class 604, subclass 246.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, I and III, and I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the claimed antithrombotics can be used in a different method of treatment. The instantly claimed fibrinolytic altepase (also known as lovastatin) can be used in a method of treating elevated cholesterol. The instantly claimed anticoagulant verapamil can be used to treat arrhythmia or angina.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention I is a composition and Invention V is a device for the administration of the composition; the composition and device have different operations, functions and effects.

Inventions II and V, III and V, and IV and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the compounds administered in the methods of treatment of thrombotic disorders and/or side effect related to the antithrombotic compounds can be administered by means other than the controlled release devise of Invention V, such as via oral delivery. Alternatively, the controlled release device of

Invention V can be used to administer compounds other than the instantly claimed compounds.

Inventions II and III, and II and IV are unrelated in that they are patentably distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different functions and different effects. One could treat a condition (Invention II) without further administering another composition to reduce side effects associated with the primary treatment (Invention III). Also, one could treat a condition (Invention II) without further administering another composition to enhance or potentialize the effects of the primary agent (Invention IV).

Inventions III and IV are unrelated in that they are patentably distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different end results: increasing efficacy of a drug versus decreasing side effects. In the instant case, a method of potentializing the effect of an administered agent (Invention IV) does would not necessarily result in preventing or reducing the effects of administering that agent (Invention III).

Election of Species

Applicant is required under 35 U.S.C. 121 to elect one of Inventions I through V, and in addition, a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

A. In the practice of the inventions defined above in Inventions I-V, items a-e) represent distinct classes of antithrombotic compounds for the practice of each one of the inventions above:

a) anti-aggregants, classified in class 558, subclass 390, for example.

b) anti-coagulants, classified in class 514, subclass 681, for example.

c) fibrinolytics, classified in class 514, subclass 453, for example.

d) thrombin inhibitors, classified in class 514, subclass 56, for example.

e) anti-vitamin K agents, classified in class 552, subclass 299, for example.

The election in item A will be given effect in the event that the Markush–type claims are not found allowable at which time the examination of the claims presented will be limited to the Markush-type claims and claims directed solely to the election made as to item A. The claims directed to nonelected items will be held withdrawn from further consideration. The election is a requirement for restriction. *In re Herrick*, 1858 CD 1, and *In re Joyce*, 19558 CD 2.

Applicant's response must include a provisional election of one of A and must include an identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a claim generic, applicant will be entitled to consideration of claims to additional species of item A above which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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